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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/673,476	11/30/2000	Stewart Cole	05394.0011	5289

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EXAMINER	
CHAKRABARTI, ARUN K	
ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 05/21/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/673,476	Cole
Examiner	**Art Unit**
Arun Chakrabarti	1634

-- ***The MAILING DATE of this communication appears on the cover sheet with the correspondence address*** --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) [X] Responsive to communication(s) filed on *Apr 14, 2003*.

2a) [ ] This action is **FINAL**. 2b) [X] This action is non-final.

3) [ ] Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) [X] Claim(s) *11, 13, 51, and 52* is/are pending in the application.

4a) Of the above, claim(s) *52* is/are withdrawn from consideration.

5) [ ] Claim(s) _____ is/are allowed.

6) [X] Claim(s) *11, 13, and 51* is/are rejected.

7) [ ] Claim(s) _____ is/are objected to.

8) [ ] Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) [ ] The specification is objected to by the Examiner.

10) [ ] The drawing(s) filed on _____ is/are a) [ ] accepted or b) [ ] objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) [ ] The proposed drawing correction filed on _____ is: a) [ ] approved b) [ ] disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) [ ] The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) [ ] Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) [ ] All b) [ ] Some* c) [ ] None of:

1. [ ] Certified copies of the priority documents have been received.
2. [ ] Certified copies of the priority documents have been received in Application No. _____.
3. [ ] Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) [ ] Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) [ ] The translation of the foreign language provisional application has been received.

15) [ ] Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) [ ] Notice of References Cited (PTO-892)
2) [ ] Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) [X] Information Disclosure Statement(s) (PTO-1449) Paper No(s). *1,2*
4) [ ] Interview Summary (PTO-413) Paper No(s). ___
5) [ ] Notice of Informal Patent Application (PTO-152)
6) [X] Other: *Detailed Action*

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 11, 13, and 51, drawn to polynucleotides.

Group II, claim(s) 52, drawn to polypeptide.

2. The inventions listed as Groups I and II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: Polynucleotides of Group I can be used to make RNA and antisense nucleic acid for gene therapy, whereas polypeptides of Group II can be used for making antibodies. Moreover, Cole et al. (Nature, (1998), Vol. 393(6685), Pages 537-544) teaches the purified polynucleotide. Therefore, claims of Group I and II lack the same or corresponding special technical features.

3. During a telephone conversation with Timothy Donaldson on April 29, 2003 a provisional election was made without traverse to prosecute the invention of Group I, claims 11, 13, and 51. Affirmation of this election must be made by applicant in replying to this Office action. Claim 52

withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Specification

5. Applicant (Timothy Donaldson) was called by the examiner on April 30, 2003 to get a clarification of the basis of the pending claims, especially claim 11, section (a), which recites nucleotide 1,695,944 through nucleotide 1,696,441 of the *Mycobacterium tuberculosis* chromosome. The specification only describes (on page 10, lines 32-35), "SEQ ID NO: 1 has now been ascribed to begin, at its 5' end at nucleotide at position nt 1696015 and to end, at its 3' end, at nucleotide at position nt 1708746". In absence of any reply from the applicant, the following office action is being forwarded to the applicant.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it

pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 11, 13, and 51 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification (on page 10, lines 32-35) discloses SEQ ID NO: 1 which corresponds to begin, at its 5' end at nucleotide at position nt 1696015 and to end, at its 3' end, at nucleotide at position nt 1708746 of the *Mycobacterium tuberculosis* chromosome. Claim 11 (a),13, and 51 are directed to encompass gene sequences, sequences that hybridize to nucleotide 1,695,944 through nucleotide 1,696,441 corresponding sequences from other species, mutated sequences, allelic variants, splice variants, sequences that have a recited degree of identity (similarity, homology), and so forth. None of these sequences meet the written description provision of 35 USC 112, first paragraph. The specification provides insufficient written description to support the genus encompassed by the claim.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention.* The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.)

With the exception of SEQ ID NO:I, the skilled artisan cannot envision the detailed chemical structure of the encompassed polynucleotides, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. The nucleic acid itself is required. In this case, nucleotide numbers 1,695,944 through nucleotide 1,696,014 of the *Mycobacterium tuberculosis* chromosome is missing from SEQ ID NO:1 See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016. In Fiddes v. Baird, 30 USPQ2d 1481, 1483, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence.

Finally, University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404, 1405 held that:

> ...To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." *Lockwood v. American Airlines, Inc.* , 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); *In re Gosteli* , 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is

claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood* , 107 F.3d at 1572, 41 USPQ2d at 1966.

An adequate written description of a DNA, such as the cDNA of the recombinant plasmids and microorganisms of the '525 patent, "requires a precise definition, such as by structure, formula, chemical name, or physical properties," not a mere wish or plan for obtaining the claimed chemical invention. *Fiers v. Revel* , 984 F.2d 1164, 1171, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993). Accordingly, "an adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself." Id. at 1170, 25 USPQ2d at 1606.

The name cDNA is not itself a written description of that DNA; it conveys no distinguishing information concerning its identity. While the example provides a process for obtaining human insulin-encoding cDNA, there is no further information in the patent pertaining to that cDNA's relevant structural or physical characteristics; in other words, it thus does not describe human insulin cDNA. Describing a method of preparing a cDNA

or even describing the protein that the cDNA encodes, as the example does, does not necessarily describe the cDNA itself.

Therefore, only nucleotide positions from 5' end nt 1696015 to its 3' end, at nucleotide at position nt 1708746 of *Mycobacterium tuberculosis* chromosome but not the full breadth of the claim (or none of the sequences encompassed by the claim) meets the written description provision of 35 USC 112, first paragraph. The species specifically disclosed are not representative of the genus because the genus is highly variant. Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 USC 112 is severable from its enablement provision. (See page 1115.).

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

9. Claims 11, 13, and 51 are rejected under 35 U.S.C. 102(a) as being anticipated by Cole et al. (Nature, (1998), Vol. 393(6685), Pages 537-544).

Cole et al. (A copy of alignment SEQ ID search enclosed herewith) teaches a purified polynucleotide, comprising an Open reading Frame contained within SEQ ID NO: 1, wherein the polynucleotide is selected from:

A) nucleotide 1696015 through nucleotide 1,696,441 of the Mycobacterium tuberculosis chromosome;

B) nucleotide 1,696,728 through nucleotide 1,697,420 of the Mycobacterium tuberculosis chromosome;

C) nucleotide 1,698,096 through nucleotide 1,699,892 of the Mycobacterium tuberculosis chromosome;

D) nucleotide 1,700,210 through nucleotide 1,701,088 of the Mycobacterium tuberculosis chromosome;

E) nucleotide 1,701,293 through nucleotide 1,702,588 of the Mycobacterium tuberculosis chromosome;

F) nucleotide 1,703,072 through nucleotide 1,704,091 of the Mycobacterium tuberculosis chromosome;

G) nucleotide 1,704,091 through nucleotide 1,705,056 of the Mycobacterium tuberculosis chromosome;

H) nucleotide 1,705,056 through nucleotide 1,705,784 of the Mycobacterium tuberculosis chromosome;

I) nucleotide 1,705,808 through nucleotide 1,706,593 of the Mycobacterium tuberculosis chromosome;

J) nucleotide 1,707,530 through nucleotide 1,708,648 of the Mycobacterium tuberculosis chromosome. (Genbank Accession No: AL 123456)(see alignment SEQ ID search report and METHODS Section, Informatics Subsection, page 543).

Cole et al inherently teaches a purified polynucleotide having a sequence fully complementary to SEQ ID NO:1 that hybridizes under stringent hybridization conditions (as specified in the instant claim 51) with the polynucleotide having SEQ ID NO:1 (METHODS Section, Informatics Subsection, page 543). This inherency is deduced from the fact that during sequence analysis by PCR method of Cole et al., all the polynucleotides and their complementary polynucleotides are synthesized and hybridized automatically.

Conclusion

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Arun Chakrabarti, Ph. D., whose telephone number is (703) 306-5818. The examiner can normally be reached on 7:00 AM-4:30 PM from Monday to Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached on (703) 308-1119. The fax phone number for this Group is (703)746-4979.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group analyst Chantae Dessau whose telephone number is (703) 605-1237.

Arun Chakrabarti,

Patent Examiner,

May 5, 2003

ARUN K. CHAKRABARTI
PATENT EXAMINER